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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,093	12/13/2006	Martin Dugas	22339-US	1715

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EXAMINER	
MUMMERT, STEPHANIE KANE	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,093	DUGAS ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a method for distinguishing MLL-PTD positive AML from other AML subtypes.

Group II, claim(s) 17-18, drawn to a use of at least one marker for manufacturing a diagnostic.

Group III, claim(s) 19-21, drawn to a kit comprising at least one marker for distinguishing MLL-PTD positive AML from other AML subtypes.

Group IV, claim(s) 22-25, drawn to an apparatus for distinguishing MLL-PTD positive AML from other AML subtypes.

Group V, claim(s) 26-27, drawn to a reference data bank comprising compiling gene expression profiles and classifying by algorithm.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The Groups are not linked by a special technical feature which distinguishes over the prior art. Armstrong et al. (Nature Genetics, 2002, vol. 30, p. 41-47) teaches gene expression profiling of tumors with MLL translocations that distinguishes the tumors from other acute leukemias (Abstract, Figure 1). Furthermore, at a minimum, the first broadest product is directed to "a diagnostic kit containing at least one marker as defined in

claim 1". Armstrong teaches detection of HOXA9 (Figure 3), which is a marker present in Table 2 of the instant invention. Therefore, the groups are not linked by a special technical feature which distinguishes over the art.

Sequence Election Requirement Applicable to Group I, IV and V

In addition, Groups I, IV and V detailed above read on patentably distinct multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Furthermore, the sequence searching in multiple expansive databases has put undue burden on the examiner and office resources. For the elected Group drawn to nucleotide sequences, the Applicants are required to elect a single nucleic acid sequence (See MPEP 803.04).

Therefore Applicant must elect a specific recognition sequence from the groups recited below. It is noted that selection of a single sequence is appropriate because claim 1, for example, requires wherein expression is observed in a sequence as indicative of a feature "and/or wherein", then the next expression feature is recited.

For Claim 1, corresponding to Group I, Applicant is required to select a single marker for which expression level will be measured from all the groups consisting of:

A polynucleotide selected from the group defined by 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, and/or 50 of Table 1;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 14, 15, 16, 18, 19, 20, 21, 22, 23, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 42, 44, 45, 47, 48, 49, and/or 50 of Table 2.1;

a polynucleotide defined by any of the numbers 10, 13, 17, 24, 25, 41, 43, and/or 46, of Table 2.1;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 19, 20, 21, 22, 23, 24, 25, 26, 28, 29, 31, 32, 33, 34, 35, 36, 38, 39, 41, 42, 44, 45, 46, 48, 49, and/or 50 of Table 2.2;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 49, and/or 50 of Table 2.3;

a polynucleotide defined by any of the numbers 34, and/or 48, of Table 2.3;

a polynucleotide defined by any of the numbers 1, 2, 3, 5, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 41, 42, 43, 44, 45, 46, 47, 48, and/or 50 of Table 2.4;

a polynucleotide defined by any of the numbers 4, 6, 7, 8, 22, 24, 40, and/or 49, of Table 2.4;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, and/or 50 of Table 2.5;

A polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 42, 43, 45, 46, 47, 48, 49, and/or 50 of Table 2.6;

a polynucleotide defined by any of the numbers 12, 15, 29, 41, and/or 44, of Table 2.6;

a polynucleotide defined by any of the numbers 1, 2, 4, 5, 7, 10, 12, 13, 16, 17, 19, 23, 25, 30, 31, 32, 33, 34, 37, 41, 43, 45, 47, 48, and/or 50 of Table 3.1;

a polynucleotide defined by any of the numbers 3, 6, 8, 9, 11, 14, 15, 18, 20, 21, 22, 24, 26, 27, 28, 29, 35, 36, 38, 39, 40, 42, 44, 46, and/or 49, of Table 3.1;

a polynucleotide defined by any of the numbers 5, 6, 9, 12, 23, 28, 38, 41, 44, 45, 46, and/or 47, of Table 3.2;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 7, 8, 10, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 42, 43, 48, 49, and/or 50 of Table 3.2;

a polynucleotide defined by any of the numbers 2, 3, 4, 6, 11, 14, 20, 22, 26, 31, 32, 33, 34, 39, 40, 41, and/or 48, of Table 3.3;

a polynucleotide defined by any of the numbers 1, 5, 7, 8, 9, 10, 12, 13, 15, 16, 17, 18, 19, 21, 23, 24, 25, 27, 28, 29, 30, 35, 36, 37, 38, 42, 43, 44, 45, 46, 47, 49, and/or 50 of Table 3.3;

A polynucleotide defined by any of the numbers 7, 31, 40, and/or 49, of Table 3.4;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 32, 33, 34, 35, 36, 37, 38, 39, 41, 42, 43, 44, 45, 46, 47, 48, and/or 50 of Table 3.4;

a polynucleotide defined by any of the numbers 1, 3, 10, 14, 17, 18, 19, 21, 24, 25, 26, 31, 32, 34, 41, 44, and/or 50 of Table 3.5;

a polynucleotide defined by any of the numbers 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 15, 16, 20, 22, 23, 27, 28, 29, 30, 33, 35, 36, 37, 38, 39, 40, 42, 43, 45, 46, 47, 48, and/or 49, of Table 3.5;

a polynucleotide defined by any of the numbers 4, 6, 9, 28, 30, 32, 35, 37, 44, 45, and/or 48, of Table 3.6;

a polynucleotide defined by any of the numbers 1, 2, 3, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18,

19, 20, 21, 22, 23, 24, 25, 26, 27, 29, 31, 33, 34, 36, 38, 39, 40, 41, 42, 43, 46, 47, 49, and/or 50 of Table 3.6;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 6, 7, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 23, 27, 28, 29, 30, 31, 32, 33, 34, 36, 38, 39, 41, 43, 44, 45, 47, 48, and/or 50 of Table 3.7;

a polynucleotide defined by any of the numbers 5, 8, 9, 19, 21, 22, 24, 25, 26, 35, 37, 40, 42, 46, and/or 49, of Table 3.7;

a polynucleotide defined by any of the numbers 7, 9, 10, 11, 13, 16, 20, 21, 22, 23, 30, 35, 36, 38, 42, 45, and/or 50 of Table 3.8;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 8, 12, 14, 15, 17, 18, 19, 24, 25, 26, 27, 28, 29, 31, 32, 33, 34, 37, 39, 40, 41, 43, 44, 46, 47, 48, and/or 49, of Table 3.8;

a polynucleotide defined by any of the numbers 1, 5, 8, 10, 11, 13, 15, 17, 19, 25, 26, 28, 29, 34, and/or 46, of Table 3.9;

a polynucleotide defined by any of the numbers 2, 3, 4, 6, 7, 9, 12, 14, 16, 18, 20, 21, 22, 23, 24, 27, 30, 31, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 47, 48, 49, and/or 50 of Table 3.9;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 28, 29, 32, 33, 36, 38, 39, 40, 43, 44, 45, 46, 47, and/or 49, of Table 3.10; a polynucleotide defined by any of the numbers 22, 27, 30, 31, 34, 35, 37, 41, 42, 48, and/or 50 of Table 3.10;

a polynucleotide defined by any of the numbers 1, 5, 6, 9, 11, 12, 15, 17, 18, 19, 23, 27, 35, 36, 37, 39, 42, 43, 47, 49, and/or 50 of Table 3.11;

a polynucleotide defined by any of the numbers 2, 3, 4, 7, 8, 10, 13, 14, 16, 20, 21, 22, 24, 25, 26, 28, 29, 30, 31, 32, 33, 34, 38, 40, 41, 44, 45, 46, and/or 48, of Table 3.11;

a polynucleotide defined by any of the numbers 1, 3, 4, 6, 7, 8, 12, 14, 15, 16, 17, 18, 19, 20, 21, 23, 25, 26, 28, 29, 30, 31, 33, 34, 35, 37, 38, 39, 42, 43, 44, 45, 47, 48, and/or 50 of Table 3.12;

a polynucleotide defined by any of the numbers 2, 5, 9, 10, 11, 13, 22, 24, 27, 32, 36, 40, 41, 46, and/or 49, of Table 3.12;

a polynucleotide defined by any of the numbers 3, 4, 7, 14, 16, 20, 22, 23, 24, 25, 26, 30, 35, 36, 37, 39, 40, 43, 44, 46, and/or 50 of Table 3.13;

a polynucleotide defined by any of the numbers 1, 2, 5, 6, 8, 9, 10, 11, 12, 13, 15, 17, 18, 19, 21, 27, 28, 29, 31, 32, 33, 34, 38, 41, 42, 45, 47, 48, and/or 49 of Table 3.13;

a polynucleotide defined by any of the numbers 13, 15, 25, 26, 27, 28, 30, 32, 33, 35, 36, 38, 39, 43, 48, and/or 49, of Table 3.14;

a polynucleotide defined by any of the numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 29, 31, 34, 37, 40, 41, 42, 44, 45, 46, 47, and/or 50 of Table 3.14;

a polynucleotide defined by any of the numbers 1, 2, 3, .4, 5, 6, 7, 8, 9, 10, 11, 13, 15, 16, 18, 19, 21, 23, 24, 25, 26, 27, 28, 29, 30, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, 43, 44, 47, 48, of Table 3.15; and

a polynucleotide defined by any of the numbers 12, 14, 17, 20, 22, 31, 37, 45, 46, 49, and/or 50 of Table 3.15.

For claim 23, corresponding to Group IV, Applicant is required to select a Table from the group consisting of Tables 1, 2, 3, 4, 5, 6 and/or 7 and a specific sequence from within the selected Table.

For claim 26, corresponding to Group V, Applicant is required to select a Table from the group consisting of Tables 1, 2, 3, 4, 5, 6 and/or 7 and a specific sequence from within the selected Table.

For the elected Group drawn to nucleotide sequences, the Applicants are required to elect a single nucleic acid sequence.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM